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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,588	09/15/2003	Sven Schreder	MERCK-2168D1	8058

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EXAMINER	
SPIVACK, PHYLLIS G	
ART UNIT	**PAPER NUMBER**
1614	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/661,588	SCHREDER ET AL.	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-6 and 9-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-6, 9-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicants' Amendment filed November 28, 2006 is acknowledged. New claims 11-16 are presented. Accordingly, claims 1, 3-6 and 9-16 are now under consideration.

A prior indication of allowable subject matter is withdrawn.

Claims 1, 3-6 and 9-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

It is unclear whether or not the term "gelatin" encompasses "gelatin capsule."

Clarification is required. It is suggested -- as a binder -- is inserted in claims 1, 9 and 10 following the recitation "gelatin." Support is provided on page 3, lines 6-7.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Upon reconsideration, claims 9 and 11-13 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4

of U.S. Patent No. 6,491,946. Although the conflicting claims are not identical, they are not patentably distinct from each other because the transitional phrase "consisting essentially of" limits the scope of claim 9 to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976).

The patent teaches pharmaceutical preparations comprising levothyroxine, potassium iodide, gelatin and fillers that are manufactured in solid form without organic solvents. See the tablet formulations in the Examples, columns 5-6. Further, as required by instant claim 12, the product is prepared in micronized form with a particle size between 5 and 25 μm. See column 2, lines 15-21. As required by instant claim 11, the amount of levothyroxine is in the range of 5 to 400 μg. See column 2, lines 9-12. The required fillers, lactose, starch and microcrystalline cellulose are conventional auxiliaries. Microcrystalline cellulose is listed in Example 2. Potassium iodide is known in the prior art as an antifungal, an expectorant and as an iodide supplement.

The present specification is drawn to embodiments that demonstrate the disclosed preparations have improved stability and can be used as a thyroid hormone preparation.

If Applicants contend that the additional material in the prior art, i.e., potassium iodide, is excluded by the recitation "consisting essentially of," Applicants have the burden of showing that the additional component would materially change the characteristics of Applicants' invention. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964).

Applicants' arguments with respect to claims 1, 3-6 and 10 that were rejected in the last Office Action under 35 U.S.C. 103 as being unpatentable over Reynolds et al., U.S. Patent 3,808,332, in view of Israel, GB 1,180,574, have been considered but are moot in view of the new ground(s) of rejection.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 9-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reynolds et al., U.S. Patent 3,808,332, in view of Schreder et al., U.S. Patent No. 6,491,946.

Reynolds teaches a combination of L-thyroxine and L-triiodothyronine that are physically admixed. Therefore, no organic solvent residues are present. See column 7, lines 65-67. See Composition I, column 7, where corn starch is employed as a filler, and Composition J, where lactose and microcrystalline cellulose are employed as fillers. As required by instant claim 3, Reynolds teaches a concentration range of l-thyroxine of 100-300 mcg. Fillers such as lactose, maize starch and microcrystalline cellulose are conventional excipients. Reynolds fails to include gelatin in the combination. However, Schreder teaches pharmaceutical preparations comprising levothyroxine, potassium iodide, gelatin and fillers that are manufactured in solid form without organic solvents. See the tablet formulations in the Examples, columns 5-6. Further, as required by

instant claim 12, the product is prepared in micronized form with a particle size between 5 and 25 µm. See column 2, lines 15-21. As required by instant claim 11, the amount of levothyroxine is in the range of 5 to 400 µg. See column 2, lines 9-12. The required fillers, lactose, starch and microcrystalline cellulose are conventional auxiliaries. Microcrystalline cellulose is listed in Example 2.

Therefore, in view of the combined teachings of Reynolds and Schreder, one skilled in the art of formulation chemistry would have been motivated to prepare pharmaceutical formulations comprising L-thyroxine and, optionally, triiodothyronine, utilizing gelatin as a binder, in a solid form without organic solvents. Further, if Applicants contend that the additional material in the prior art, e.g., potassium iodide, is excluded by the recitation "consisting essentially of," Applicants have the burden of showing that the additional component would materially change the characteristics of Applicants' invention. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964).

No claim is allowed.

Coleman, H.D., WO 93/04691, is cited to show further the state of the art. Coleman teaches pharmaceutical preparations comprising thyroxine and triiodothyronine and gelatin in solid formulations. See claims 32 and 38, as well as page 17, lines 16-18. No organic solvents are noted in the manufacture of said preparations.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phyllis Spivack

March 1, 2007

Phyllis G. Spivack
1614

PHYLLIS SPIVACK
PRIMARY EXAMINER